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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,668	12/18/2001	Stephen Griffin	1001.1535101	6574

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 06/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/025,668

Applicant(s)

GRIFFIN ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 - 35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 and 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statements filed 3/26/02 and 12/16/02 comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. The information disclosure statements have been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

Specification

1. The disclosure is objected to because of the following informalities: Line 6, Page 5 begins, "elongate shaft 100". It appears that in Figure 1 the "elongate shaft" is referenced by numeral 102. Previously, the reference numeral 100 has been used to point out the "intravascular device" and the "balloon catheter".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 17 – 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,662,621 to Lafontaine.

In reference to claims 1, 2, 20 and 21, Lafontaine discloses applicant's claimed invention including a stainless steel metal elongate core wire (24) having an elastic limit (Col. 5, line 64 – 66); and a polymer jacket (22; Col. 5, lines 24 – 26) surrounding a distal portion of the core wire having an elastic limit, the jacket being more stiff than the distal portion of the core wire which it surrounds

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so that when deformed into a shape within the elastic limit of the metal and beyond the elastic limit of the polymer, the tip retains the shape in that once the polymer jacket acquires its stiff, memory retention shape, the core wire has the shape provided by the jacket (Col. 5, lines 46 – 59).

In reference to claims 17 – 19, Lafontaine discloses applicant's claimed method including deforming the polymer jacket and the core wire into a shape; heating the deformed polymer jacket to a temperature at or above the glass transition temperature of the shape memory polymer (Col. 5, lines 49 – 56); and cooling the deformed jacket to a temperature below the glass transition temperature of the shape memory polymer to maintain the shape (Col. 5, lines 56 – 59). Lafontaine discloses reheating and cooling the jacket to form and maintain different shapes including the original shape (Col. 7, lines 24 – 34).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3, 4, 22 and 23 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S.

Patent No. 5,662,621 to Lafontaine in view of U.S. Patent No. 5,772,609 to Nguyen et al.

In reference to claims 3, 4, 22 and 23, Lafontaine discloses the elongate core wire comprising a metal (Col. 5, line 64 – 66), but fails to disclose the metal being a super elastic metal comprising a nickel titanium alloy. Nguyen et al. teaches forming the elongate core wire of either stainless steel or a super elastic metal comprising a nickel titanium alloy (Col. 4, lines 44 – 48). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the

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metal of the elongate core wire as disclosed by Lafontaine to include a super elastic metal comprising a nickel titanium alloy as taught by Nguyen et al. in that Nguyen et al. teaches the two metals forming the elongate core wire to be interchangeable (Col. 4, liens 44 – 48). Additionally, the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In the present case, modifying the elongate core wire as disclosed by Lafontaine to be formed of a super elastic metal comprising a nickel titanium alloy is a design consideration within the skill of the art.

6. Claims 5 – 16 and 24 – 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,662,621 to Lafontaine in view of U.S. Patent No. 6,485,458 to Takahashi. In reference to claims 5 – 16 and 24 – 35, Lafontaine discloses a shape memory polymer surrounding a portion of the core wire, but fails to disclose the polymer being polyurethane, polynorbornene, polcaprolactone, polymethylmethacrylate, PLLA, PLLA OGA, PL/D LA, PMMA, polyethylene, polyisoprene, styrene-butadiene or photocrosslinkable polymer. However, Takahashi discloses a shape memory polymer surrounding a core wire wherein the polymer consists of poluorbornen, styrene-butadiene, polyurethane, polyisoprene, polyester, polyolefin, acrylic and styrene-acrylic (Col. 5, lines 56 – 67). Takahashi teaches that other shape-memory materials can be used in addition to those disclosed. It would have been obvious to one having ordinary skill in the art at the time the invention was made use any shape memory polymer as taught by Takahashi in the device as disclosed by Lafontaine in that Takahashi teaches that shape memory polymers are interchangeable. Additionally, the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In the present case, replacing the shape memory polymer as disclosed by

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Lafontaine with any other shape memory polymer is a design consideration within the skill of the art.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following U.S. Document are cited because they disclose the use of shape memory polymers as disclosed by applicant: Hurst et al., Lee et al., Choi et al., Hoenig et al. and Hupp.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-308-0758 for regular communications and (703)-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.



JMLF
June 2, 2003



MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
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